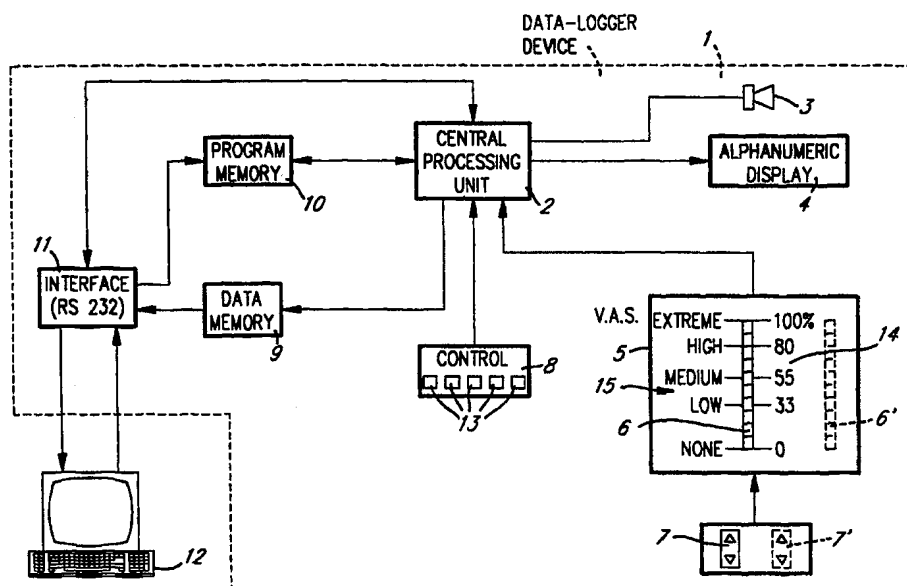




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(21) International Application Number: PCT/CA97/00544 (22) International Filing Date: 30 July 1997 (30.07.97) (71) Applicant: UNIVERSITE DE MONTREAL [CA/CA]; 2900 Édouard-Montpetit, Montreal, Quebec H3T 1J4 (CA). (72) Inventors: DAIGLE, Serge; 301 Lauzon, Rouyn Noranda, Quebec J9X 3T8 (CA). MARCHAND, Serge; 11 MacDonald, Rouyn Noranda, Quebec J9X 1A3 (CA). BUSHNELL, Catherine; 772 A Bloomfield, Outremont, Quebec H2V 3S3 (CA). LAVIGNE, Gilles; 319 Monmouth, Ville Mont-Royal, Quebec H2P 2B3 (CA). SAINT-JACQUES, Sylvain; 808 Rabelais, Deux-Montagnes, Quebec J7R 6S2 (CA). (74) Agents: DUBUC, Jean, H. et al.; Goudreau Gage Dubuc & Martineau Walker, The Stock Exchange Tower, Suite 3400, 800 Place Victoria, P.O. Box 242, Montreal, Quebec H4Z 1E9 (CA).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: PORTABLE AND PROGRAMMABLE INTERACTIVE VISUAL ANALOGUE SCALE DATA-LOGGER DEVICE



(57) Abstract

A portable, interactive clinical data-logger device signals to a patient under investigation a succession of recording time periods spaced apart by predetermined time intervals. After a recording time period has been signalled, questions such as "What intensity of pain are you feeling?", "What degree of discomfort are you feeling?" or "How severe is a given symptom?" are displayed. The patient answers each question by means of a pushbutton-controlled bar graph associated to a pain intensity, discomfort degree and/or symptom severeness representative V.A.S. scale. The V.A.S. data are then stored and available for further processing into an outside computer.

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5

PORTABLE AND PROGRAMMABLE INTERACTIVEVISUAL ANALOGUE SCALE DATA-LOGGER DEVICE

10

BACKGROUND OF THE INVENTION1. Field of the invention:

15

The present invention relates to a portable clinical data-logger device of the visual analogue scale (V.A.S.) type to be carried by the patient. This data-logger device is both interactive and programmable, and finds wide applicability in research and clinical practice.

20

2. Brief description of the prior art:

25

The company **Autenta AB**, Box 9028, S-750 09 Uppsala, Sweden is fabricating and commercializing a data-logger of the above type, under the name SYMTRACK®. The SYMTRACK® data-logger is portable and carried by the patient to record the intensity/severity of a given symptom in time.

30

5 The SYMTRACK® data-logger emits a signal to remind the patient of each recording procedure. User selectable sample periods of 1, 5 or 10 minutes are available.

10 At each recording, the patient indicates by means of a visual analogue scale (V.A.S.) the intensity/severity of the symptom. Corresponding symptom data are then recorded and available for analysis purposes.

15 By concealing previous recordings from the patient, the SYMTRACK® data-logger prevents the patient to enter symptom data retrospectively. As retrospective symptom data are notoriously inaccurate, 20 the SYMTRACK® data-logger substantially improves the accuracy of the collected data.

 The SYMTRACK® data-logger presents the following drawbacks:

25 - programming is limited (for example, a very limited number of user selectable sample periods are available);

30 - data relative to only one symptom can be recorded at a time.

5

OBJECTS OF THE INVENTION

10 An object of the present invention is
therefore to provide a portable visual analogue scale
data-logger device which is fully programmable.

15 Another object of the present invention is
to provide a portable visual analogue scale data-
logger device which is interactive to enable recording
at the same time of different types of clinical data.

SUMMARY OF THE INVENTION

20

25 More specifically, in accordance with the
present invention, there is provided a portable,
interactive data-logger device for recording clinical
data relative to a patient under investigation,
comprising:

timer means for signalling to the patient
a succession of recording time periods spaced apart by
predetermined time intervals;

5 means for communicating a message to the patient after a recording time period has been signalled;

data-entering means for allowing the patient to enter clinical data relative to the patient and related to the message; and

10

memory means for receiving and storing the entered clinical data.

In accordance with preferred embodiments of the portable, interactive data-logger device of the invention:

15

- the message communicating means comprises a display unit for displaying a question to be answered by the patient;

20

- the portable, interactive data-logger device further comprises means for turning the data-logger device on, the message communicating means then comprising means for communicating a message to the patient following turning on of the data-logger device;

25

- the portable, interactive data-logger device further comprises means for preventing the patient to enter or alter any data entered during one

30

5 recording time period after this recording time period
has elapsed;

 - the message asks to the patient what
intensity of pain he is feeling, what degree of
10 discomfort he is feeling, and/or how severe is a given
symptom, the data-entering means comprises means for
allowing the patient to enter the intensity of pain he
is feeling, the degree of discomfort he is feeling
and/or the severeness of the given symptom;

15

 - the data-entering means comprises a bar
graph, scale means along the bar graph, and pushbutton
means for controlling the bar graph;

20

 - the time intervals between the
successive recording time periods and the message to
be communicated to the patient after a recording time
period has been signalled are fully programmable; and

25

 - the message communicating means
comprises means for communicating to the patient a
plurality of messages, and the data-entering means
comprises means for allowing the patient to enter
clinical data related to each message.

30

5 The objects, advantages and other features
of the present invention will become more apparent
upon reading of the following non restrictive
description of a preferred embodiment thereof, given
by way of example only with reference to the
10 accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

15

In the appended drawings:

Figure 1 is a schematic block diagram of
the preferred embodiment of the portable and
20 programmable interactive visual analogue scale
(V.A.S.) data-logger device according to the
invention, comprising a central processing unit, an
electroacoustic transducer, an alphanumeric display,
a V.A.S. including a bar graph controllable through an
25 up/down pushbutton switch, a control keyboard, a data
memory, a program memory and an RS 232 port interface;
and

Figure 2 is a flow chart showing operation
30 of the portable and programmable interactive visual

5 analogue scale (V.A.S.) data-logger device of Figure
1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

10

Referring to Figure 1 of the appended drawings, the portable and programmable interactive visual analogue scale (V.A.S.) data-logger device 1,
15 hereinafter referred to as "data-logger device 1" comprises:

- a central processing unit 2;
- 20 - an electroacoustic transducer 3
connected to the central processing unit 2;
- an alphanumeric display 4 connected to
the central processing unit 2;
- 25 - a V.A.S. unit 5 connected to the central
processing unit 2 and including a bar graph 6
controllable through an up/down pushbutton switch 7;

5 - a control keyboard 8 comprising a plurality of keys 13 and connected to the central processing unit 2;

 - a data memory 9 connected to the central
10 processing unit 2;

 - a program memory 10 in bidirectional communication with the central processing unit 2; and

15 - an RS 232 port interface 11 connectable to an outside personal computer 12 to establish bidirectional communication between the personal computer 12 and the central processing unit 2, unidirectional communication from the personal
20 computer 12 to the program memory 10 and unidirectional communication from the data memory 9 to the personal computer 12.

 Reference will now be made to both Figures
25 1 and 2 to describe operation of the data-logger device 1.

 The data-logger device 1 is programmed (step 20 of Figure 2) for recording clinical data
30 relative to a patient under investigation. Programming is carried out by means of the personal

5 computer 12 through the RS 232 port interface 11.
More specifically, the personal computer 12
communicates with the central processing unit 2 to
store the new program in the memory 10.

10 In particular, successive recording time
periods spaced apart by predetermined time intervals
are programmed along with questions to be answered by
the patient at each recording time period. Different
questions may be asked to the patient at successive
15 recording time periods, and the time intervals between
the successive recording time periods is programmable
at will.

Examples of questions that can be asked to
20 the patient are the following:

- What intensity of pain are you
feeling?;
- 25 - What degree of discomfort are you
feeling?;
- How severe is (a given symptom) ?;
- 30 - etc.

5 A timer is incorporated in the central
processing unit 2 to allow this central processing
unit 2 to signal to the patient each recording time
period (step 21 of Figure 2). This is carried out by
the central processing unit 2 by emitting a sound
10 signal through the electroacoustic transducer 3.

In response to the sound signal emitted
through the electroacoustic transducer 3, the patient
should turn the data-logger device 1 on (step 22 of
15 Figure 2) by depressing one of the keys 13 of the
control keyboard 8.

Each recording time period has a given
length. After a recording time period has been
20 signalled, the central processing unit 2 counts time.
After the recording time period has elapsed (step 23
of Figure 2) the program returns to step 21 and the
patient is no longer enabled to enter and/or alter any
data related to this particular recording time period.
25 A corresponding message is then displayed (step 24 of
Figure 2) on the alphanumeric display 4. This
prevents the patient to enter data retrospectively,
retrospective data being as mentioned in the foregoing
description notoriously inaccurate.

5 As long as the recording time period has
not elapsed (step 23 of Figure 2), the patient is
enabled to enter data. It should be pointed out here
that the length of the recording time periods is well
sufficient to allow the patient to enter the clinical
10 data related to the questions.

 If the recording time period is not
elapsed, the central processing unit 2 is responsive
to turning on of the data-logger device 1 to display
15 on the alphanumeric display 4 a message, in particular
but not exclusively a question to be answered by the
patient (step 25 of Figure 2).

 For example, if the question is "What
20 intensity of pain are you feeling?", the patient
operates the up/down pushbutton switch 7 (step 26 of
Figure 2) to control the bar graph 6 so as to indicate
the intensity of pain he is feeling on the 0-100%
scale 14 (Figure 1) appearing along that bar graph 6.
25 To facilitate answering by the patient, indications
such as NONE, LOW, MEDIUM, HIGH and EXTREME (see 15 in
Figure 1) are distributed along the scale 14.

 The patient then depress an "ENTER" key
30 (step 27 of Figure 2) amongst the keys 13 of the
keyboard 8 to command the central processing unit 2 to

5 store or record in the memory 9 the V.A.S. data
indicative of the intensity of the pain the patient is
feeling (step 28 of Figure 2).

10 If the patient has to answer another
question (step 29 of Figure 2) in the same recording
time period, the program of the central processing
unit 2 returns to step 25 and steps 25-28 are repeated
for the additional question. Therefore, many
questions may be asked to the patient during each
15 recording time period.

 As another example, if the question is
"What degree of discomfort are you feeling?", the
patient operates the up/down pushbutton switch 7 to
20 control the bar graph 6 so as to indicate the degree
of discomfort he is feeling on the 0-100% scale 14
(Figure 1) taking into consideration the indications
15.

25 The questions "What intensity of pain are
you feeling?" and "What degree of discomfort are you
feeling?" can be combined and the V.A.S. unit provided
with two bar graphs 6 and 6' respectively controlled
through up/down pushbutton switches 7 and 7'. To
30 answer, the patient operates the up/down pushbutton
switches 7 and 7' to indicate the intensity of pain

5 through the bar graph 6 and the degree of discomfort
he is feeling through the bar graph 6', that is on the
0-100% scale 14 (Figure 1) taking into consideration
the indications 15. Depression of the "ENTER" key of
the keyboard 8 (step 27) will then cause recording of
10 both V.A.S. data (step 28) related to the intensity of
pain and degree of discomfort.

Another possible question is "How severe
is (a given symptom) ? ". Again, to answer that
15 question the patient operates the up/down pushbutton
switch 7 to indicate, by means of the bar graph 6, how
severe is the symptom of concern on the 0-100% scale
14 (Figure 1) taking into consideration the
indications 15.

20 Those skilled in the art will appreciate
that a plurality of other messages such as questions
can be contemplated to collect clinical data
concerning a given patient and related to these
25 messages. The present invention is in no way limited
by the type of messages.

When no additional question is to be
answered (step 29 of Figure 2), an "END" message is
30 displayed on the alphanumeric display 4 (step 30 of

5 Figure 2). The patient then turns the data-logger device 1 off (step 31 of Figure 2).

 The V.A.S. data collected in the memory 9 can be retrieved by the outside personal computer 12 through the RS 232 port interface 11 and through appropriate commands transmitted to the central processing unit 2. The collected data can then be processed as desired in the computer 12.

15 The dimensions of the portable data-logger device 1 are as reduced as possible to be easily carried by the examiner. Acceptable dimensions are those of an electronic calculator.

20 Although the present invention has been described hereinabove by way of a preferred embodiment thereof, this embodiment can be modified at will, within the scope of the appended claims, without departing from the spirit and nature of the subject invention.

25

WHAT IS CLAIMED IS:

1. A portable, interactive data-logger
5 device for recording clinical data relative to a
patient under investigation, comprising:

timer means for signalling to the patient
a succession of recording time periods spaced apart by
predetermined time intervals;

10 means for communicating a message to the
patient after a recording time period has been
signalled;

data-entering means for allowing the
patient to enter clinical data relative to the patient
15 and related to the message; and

memory means for receiving and storing the
entered clinical data.

2. A portable, interactive data-logger
20 device as recited in claim 1, in which said message
communicating means comprises a display unit for
displaying a question to be answered by the patient.

3. A portable, interactive data-logger
25 device as recited in claim 1, further comprising means
for turning the data-logger device on, wherein said
message communicating means comprises means for

communicating a message to the patient following turning on of the data-logger device.

5 4. A portable, interactive data-logger device as recited in claim 1, further comprising means for preventing the patient to enter or alter any data entered during one of said recording time periods after said recording time period has elapsed.

10 5. A portable, interactive data-logger device as recited in claim 1, wherein:

 said message communicating means comprises means for asking to the patient what intensity of pain he is feeling; and

15 said data-entering means comprises means for allowing the patient to enter the intensity of pain he is feeling.

20 6. A portable, interactive data-logger device as recited in claim 5, wherein said means for allowing the patient to enter the intensity of pain he is feeling comprises:

 - a bar graph;
 - pain intensity scale means along said
25 bar graph; and
 - pushbutton means for controlling said bar graph.

7. A portable, interactive data-logger device as recited in claim 1, wherein:

said message communicating means comprises means for asking to the patient what degree of discomfort he is feeling; and

said data-entering means comprises means for allowing the patient to enter the degree of discomfort he is feeling.

8. A portable, interactive data-logger device as recited in claim 7, wherein said means for allowing the patient to enter the degree of discomfort he is feeling comprises:

- a bar graph;
- discomfort degree scale means along said bar graph; and
- pushbutton means for controlling said bar graph.

9. A portable, interactive data-logger device as recited in claim 1, wherein:

said message communicating means comprises means for asking to the patient how severe is a given symptom; and

said data-entering means comprises means for allowing the patient to enter the severeness of said given symptom.

10. A portable, interactive data-logger device as recited in claim 9, wherein said means for allowing the patient to enter the severeness of said given symptom comprises:

- 5 - a bar graph;
- symptom severeness scale means along said bar graph; and
- pushbutton means for controlling said bar graph.

10

11. A portable, interactive data-logger device as recited in claim 1, wherein:

- said message communicating means comprises means for asking to the patient both what intensity of
- 15 pain and what degree of discomfort he is feeling; and
- said data-entering means comprises means for allowing the patient to enter both the intensity of pain and the degree of discomfort he is feeling.

20

12. A portable, interactive data-logger device as recited in claim 11, wherein said means for allowing the patient to enter the intensity of pain and the degree of discomfort he is feeling comprises:

- a first bar graph;
- 25 - pain intensity scale means along said first bar graph;
- first pushbutton means for controlling said first bar graph;

- a second bar graph;
- discomfort degree scale means along said second bar graph; and
- second pushbutton means for controlling said second bar graph.

5

13. A portable, interactive data-logger device as recited in claim 1, comprising means for programming the time intervals between the successive recording time periods.

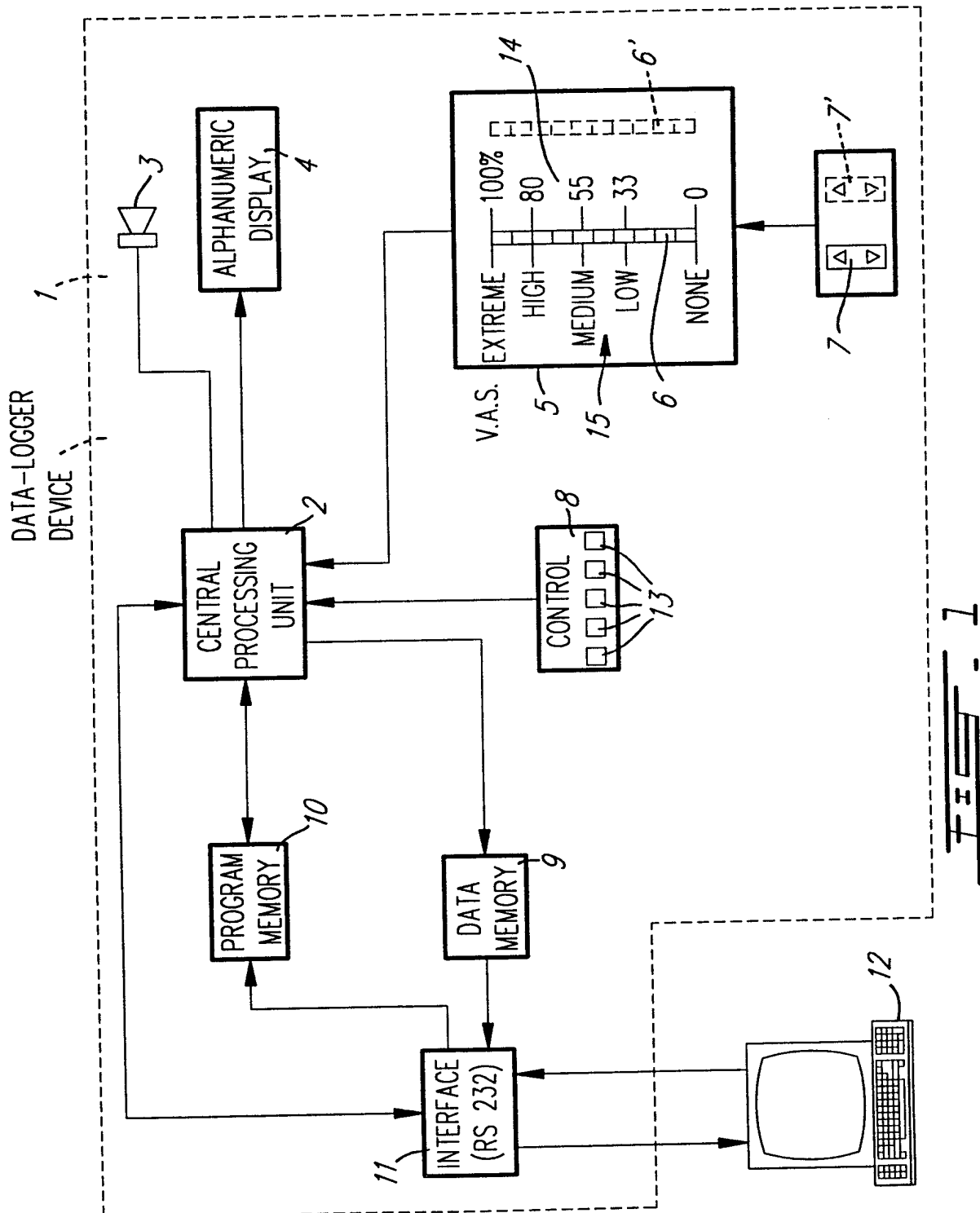
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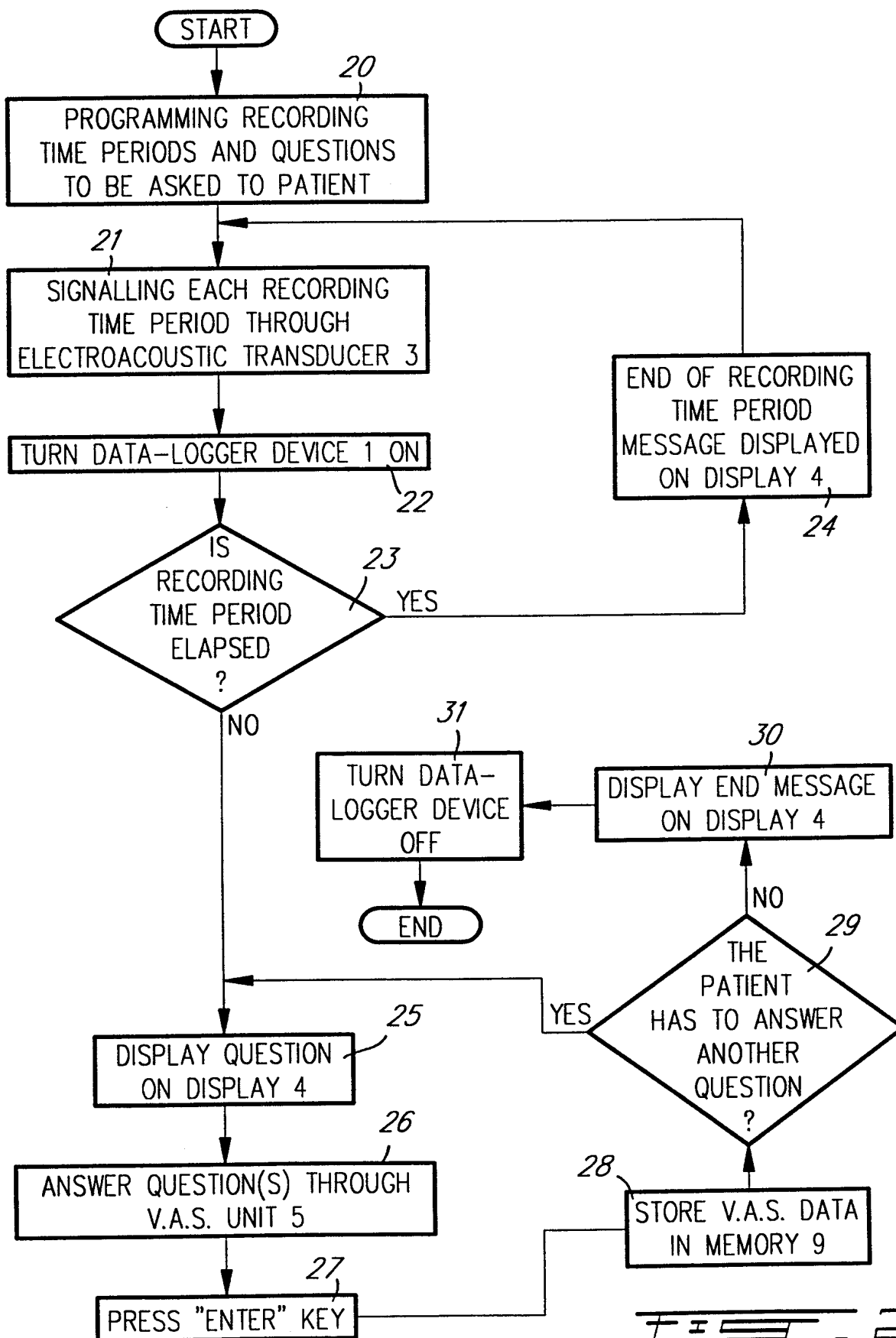
14. A portable, interactive data-logger device as recited in claim 1, comprising means for programming the message to be communicated to the patient after a recording time period has been signalled.

15

15. A portable, interactive data-logger device as recited in claim 1, wherein said message communicating means comprises means for communicating to the patient a plurality of messages, and wherein said data-entering means comprises means for allowing the patient to enter clinical data related to each of said messages.

20





INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 97/00544

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 29007 A (WALKER DAVID JOHN) 26 September 1996	1
A	see page 10, line 12 - page 11, line 16	5-8,10,13,14
	see page 13, line 11 - page 18, line 7	
	see page 21, line 18 - page 22, line 15;	
	tables 1-3,11	

Y	EP 0 212 278 A (CARDIAC MONITORING SERV INC) 4 March 1987	1
A	see page 9, line 4 - page 34, line 16;	2,3,15
	table 1	

A	FR 2 727 850 A (ELA MEDICAL SA) 14 June 1996	1,3,15
	see abstract	
	see page 5, line 16 - page 9, line 24;	
	table 1	

	-/-	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

23 February 1998

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INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 5 577 510 A (CHITTUM WILLIAM R ET AL)</p> <p>26 November 1996</p> <p>see column 4, line 32 - column 5, line 62;</p> <p>tables 1-3</p> <p>-----</p>	1,15

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Information on patent family members

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